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16. Abstract (Limit: 200 words)

This document contains up-to-date chemical information, including a summary of the Agency's regulatory position and rationale, on a specific pesticide or group of pesticides. A Fact Sheet is issued after one of the the following actions has occurred.

1. Issuance or reissuance of a registration standard,
2. Issuance of each special review document,
3. Registration of a significantly changed use pattern,
4. Registration of a new chemical, or
5. An immediate need for information to resolve controversial issues relating to a specific chemical or use pattern.

17. Document Analysis a. Descriptors

Pesticides, regulations, Chemical Information Fact Sheet, Use Patterns, science findings.

b. Identifiers/Open-Ended Terms

c. COSATI Field/Group

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EPA

Pesticide Fact Sheet

Name of Chemical: AMITRAZ
Reason for Issuance: REGISTRATION STANDARD
Date Issued: OCT 1987
Fact Sheet Number: 147

1. DESCRIPTION OF CHEMICAL

- Generic Name: N'-(2,4-dimethylphenyl)-N-[[(2,4-dimethyl=phenyl)imino]methyl]-N-methylmethanimidamide
- Common Name: Amitraz
- Trade Name: Baam, Taktic
- EPA Shaughnessy Code: 106201
- Chemical Abstract Service (CAS) Number: 33089-61-1
- Year of Initial Registration: 1975
- Pesticide Type: Insecticide/Acaricide
- Chemical Family: Diamidides
- U.S. Producer: Nor-Am Chemical Company

2. USE PATTERNS AND FORMULATIONS

- Application sites: pears
- Types and methods of applications: aerial and ground application as a spray
- Application rates: 0.75 lb active ingredient (ai)/A to 1.5 lb ai/A
- Usual Carriers: Confidental business information

3. SCIENCE FINDINGS

- In summary, amitraz is a diamidide compound of moderate mammalian acute toxicity but has been shown to be carcinogenic in mice. The Agency has concluded that amitraz is a borderline C/D carcinogen. Other toxicology studies do not demonstrate other significant chronic effects. Amitraz's behavior in the environment is not well defined. Its acute toxicity to birds is low, although it may affect reproduction, it is moderately toxic to aquatic species. Additional studies are being required for environmental fate and ecological effects.

Chemical Characteristics

- Technical amitraz is a straw colored crystalline solid. Its melting point is 86-87°C.
- It is extremely soluble in xylene and acetone and is very insoluble in water.
- Amitraz is relatively stable to heat, however the stability of amitraz in water is poor. Additional data are being required in order to determine the sensitivity of amitraz to metal ions and metal.

Toxicology Characteristics

- Acute oral: 523 mg/kg, Toxicity Category III.
- Acute dermal: >200 mg/kg, Toxicity Category II.
- Primary Eye Irritation: Non-irritating, Toxicity Category IV
- Acute Inhalation: 2.40 mg/l, Toxicity Category III.
- Primary Skin Irritation: Nonirritant, Toxicity Category IV.
- Skin Sensitization: Not a sensitizer.
- Major Routes of Exposure: Human exposure from amitraz applications is greatest from mixing and loading of pesticide formulation and applying it. Exposure can be reduced by the use of goggles or face shield and gloves and other protective clothing.
- Neurotoxicity: Amitraz is not expected to be a delayed neurotoxin because it is neither an organophosphate or an analog of a neurotoxic compound.
- Oncogenicity: A 2-year rat feeding and oncogenicity study was negative at 200 ppm. An 80-week mouse oncogenicity study demonstrated an increase in lymphoreticular tumors in female mice but not in males at 400 ppm. A 2-year mouse oncogenicity study demonstrated an increase in hepatocellular tumors in female mice at the 400 ppm level. The 2-year mouse study was referred to the Agency's Cancer Assessment Group (CAG) for evaluation. CAG determined, based on the weight of the evidence, that amitraz is in the lower portion of the Group "C" range. The SAP concluded that amitraiz should be classified as a Group "D", (not classifiable as to human carcinogenicity) because they believed the weight of the evidence was inadequate to clearly categorize the oncogenic potential of amitraz. The Agency has reassessed its own position in light of the SAP position and has now concluded that amitraz is a borderline Class C/D carcinogen.
- Metabolism: Available data suggest that amitraz is not readily absorbed in tissues and is excreted in the urine.
- Teratology: A teratology study in the rat was negative at 12 mg/kg body weight (bwt). A teratology study in the rabbit was negative at 25 mg/kg bwt.
- Reproduction: A 3-generation rat reproduction study was negative at 15 ppm.

- Mutagenicity: Available data show amitraz to be negative in the gene mutation, host mediated and dominant lethal test systems. Additional negative mutagenic studies were conducted in the Mouse Lymphoma Mutation Assay, Ames Bacterial Mutagenicity Test and in Unscheduled DNA Synthesis in Human Embryonic Cells.

Physiological and Biochemical Characteristics

- Mechanism of action: Amitraz causes depression of hypothalamic function.
- Metabolism and persistance in plants and animals: The metabolism of amitraz in plants has not been adequately described. Additional data are required. Data pertaining to the metabolism of amitraz in food producing animals are not required because there are no finite tolerances established for amitraz residues on crops involving livestock feed items.

Environmental Characteristics

- Available data are insufficient to fully assess the environmental fate of amitraz. Data gaps exist for all required studies.
- The available data do suggest that amitraz can leach slowly in certain soils. Data are required to assess amitraz's environmental fate and ability to leach through soils.

Ecological Characteristics

- Avian acute oral (LD_{50}) toxicity: 788 mg/kg for bobwhite quail (slightly toxic).
- Avian dietary (LC_{50}) toxicity: 7000 ppm for mallard duck (slightly toxic).
- Avian reproduction: No observable effect level (NOEL) is <40 ppm. A new study is required to demonstrate a NOEL.
- Freshwater fish acute (LC_{50}) toxicity: cold water species (rainbow trout)--0.74 ppm for technical; warm water species (bluegill)--1.34 ppb for technical.
- Aquatic freshwater invertebrates toxicity: Daphnia--35.0 ppb.
- Additional data are required to fully characterize the ecological effects of amitraz.

Required Unique Labeling Summary

All manufacturing-use and end-use amitraz products must bear appropriate labeling as specified in 40 CFR 162.10. In addition to the above, the following information must appear on the labeling:

- Manufacturing-use products must state that they are intended for formulation into other manufacturing-use products or end-use products only for use on pears, cattle and hogs.

- The Agency is removing the Restricted Use Classification for amitraz since the weight of the evidence is inadequate to clearly catagorize the oncogenic potential of amitraz. will specify the reason (oncogenicity).
- A reentry interval of 24 hours will continue to be required for the pear use until data required by the standard are received and evaluated.
- Worker protection statements will be required for all end-use amitraz products.

Tolerance Assessment

- The Agency is unable to complete a full tolerance assessment because the metabolism of amitraz in plants has not been adequately described.
- The available data support the established tolerances for pears, cattle and hogs.
- Established tolerances are published in 40 CFR 180.287 and they are:

Commodity	Parts Per Million
Pears	3.0
Apples	0.0
Cattle, fat	0.1
Cattle, meat byproducts (mbyp)	0.3
Cattle, meat	0.05
Milk	0.03
Goats, fat	0.0
Goats, mbyp	0.0
Goats, meat	0.0
Hogs, fat	0.3
Hogs, mbyp	0.3
Hogs, meat	0.05
Hogs, kidney and liver	0.2
Horses, fat	0.0
Horses, mbyp	0.0
Horses, meat	0.0
Sheep, fat	0.0
Sheep, mbyp	0.0
Sheep, meat	0.0

- The Agency established the above zero tolerances to reflect, in part, its conclusion of the Rebuttable Presumption Against Registration (RPAR) (1979) not to permit the use of amitraz on apples and therefore not to permit residues in apples or meat producing animals which consume apple processing waste.

- The acceptable daily intake (ADI) for amitraz is 0.0025 mg/kg/day based on a 2-year dog study with a NOEL of 10 ppm and a safety factor of 100. The maximum permitted intake (MPI) (based on a 60 kg person) is 0.15 mg/day. The published tolerances provide a theoretical maximum residue contribution (TMRC) to the daily diet of 0.0723 mg/day (for an average 1.5 kg daily diet) which accounts for 48.20% of the ADI.

4. SUMMARY OF REGULATORY POSITION AND RATIONALE

- The Agency has determined that it should continue to allow the registration of amitraz for use on pears, cattle and hogs. Other uses will be considered on a case-by-case basis.
- The toxicology data base for amitraz is complete. The Agency's has determined that amitraz should be classified as a Group C/D carcinogen.
- Available data are insufficient to fully assess the environmental fate of and the ecological effects from amitraz. Data are required to determine if amitraz will contaminate ground water.

5. SUMMARY OF MAJOR DATA GAPS

- The full complement of environmental fate data requirements including studies on degradation (hydrolysis and photolysis), soil metabolism, mobility, dissipation, and accumulation
- An avian reproduction study
- A plant metabolism study

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